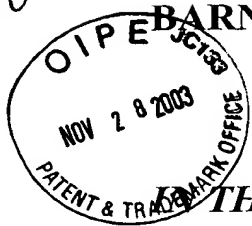


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THE UNITED STATES PATENT AND TRADEMARK OFFICE

Customer No. 23643

Group: 1617

Confirmation No.: 9728

Application No.: 09/923,118

Invention: BIOERODABLE POLYMERIC
ADHESIVES FOR TISSUE REPAIR

Inventor: Peterson, et al.

Filed: August 6, 2001

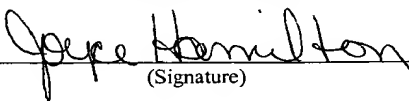
Attorney Docket: 265280-68798

Examiner: Edward J. Webman

Certificate Under 37 CFR 1.8(a)

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on November 24, 2003


(Signature)

Joyce Hamilton
(Printed Name)

TRANSMITTAL OF APPEAL BRIEF

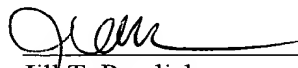
Mail Stop Appeal Brief - Patents

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

A Notice of Appeal of the Examiner's final rejection of claims 13-18 of the captioned application was mailed on October 1, 2003. The Appeal Brief is submitted herewith in triplicate. Our Check No. 332980 in the amount of \$330.00 is enclosed for payment of fee under 37 C.F.R. § 1.17(c) for filing a brief in support of an appeal. The Commissioner is hereby authorized to charge any additional fees, or to credit any overpayment, to our Deposit Account No. 10-0435 with reference to our matter number 265280-68798.

Respectfully submitted,
BARNES & THORNBURG



Jill T. Powlick
Attorney Registration No. 42,088
(317) 231-7504 INDS02 JTP 622034v1



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(Signature)

Joyce Hamilton
(Printed Name)

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellant appeals from the final rejection dated October 1, 2003, of claims 13-18.

Claims 1-12 remain pending and have been allowed.

REAL PARTY IN INTEREST

The real party in interest is DePuy Orthopaedics, Inc., the assignee, pursuant to an assignment by Boehringer Mannheim Corporation, recorded in the U.S. Patent and Trademark Office at Reel 8563, Frame 0469 on June 12, 1997, for the rights in the immediate parent application, U.S. Patent Application No. 08/633,102, now U.S. Patent No. 6,299,905. Inventors Dale R. Peterson, David Z. Deng, and Todd P. Glancy assigned their rights to Boehringer Mannheim Corporation in an assignment recorded in the U.S. Patent and Trademark Office at Reel 8285, Frame 0592 on December 23, 1996. The present application

is a continuation of U.S. Patent Application No. 08/633,102, now U.S. Patent No. 6,299,905.

RELATED APPEALS AND INTERFERENCES

There are no other pending appeals or interferences related to the present appeal.

STATUS OF CLAIMS

Claims 1-12 are allowed. Claims 13-18 are finally rejected. The final rejection of claims 13-18 is being appealed.

STATUS OF AMENDMENTS

The application as filed presented claims 1-12. By appellant's response mailed June 5, 2002, claims 1, 11, and 12 were amended and claims 13-18 were added. Although only the rejection of claims 13-18 is being appealed, the entire pending claim set, claims 1-18 as currently amended, is attached as Appendix A.

SUMMARY OF THE INVENTION

The present invention is directed to a pressure sensitive adhesive for tissue repair comprising a thermoplastic lactide-containing terpolymer of monomer units derived from lactic acid, glycolic acid, and either caprolactone or valerolactone (see page 9, lines 3-9; page 16, line 26 to page 17, line 30; page 22, lines 16-19), the terpolymer exhibiting an adhesive strength of about 600 to about 150,000 Pa (see page 2, line 14) and having a water solubility of 0.01 to about 500 mg/ml at about 25°C (see page 2, lines 4-5). In some embodiments, the terpolymer has an average molecular weight of 1,000 to 3,000 (see page 9, line 5-6) and a glass transition temperature of less than 0°C (see page 2, lines 10-12; page 34, lines 17-18).

ISSUES

The issues presented by this appeal are:

(a) whether the invention defined in rejected claims 13-16 is anticipated within the meaning of 35 U.S.C. § 102(b) over Brine (U.S. Patent No. 5,075,115), and

(b) whether the term “derived” in claims 13-18 is vague and renders claims 13-16 indefinite under 35 U.S.C. § 112, second paragraph.

GROUPING OF THE CLAIMS

Claims 13-16 stand or fall together for the rejection under 35 U.S.C. § 102(b). Claims 13-18 stand or fall together for the rejection under 35 U.S.C. § 112, second paragraph.

Claims 1-12 have been allowed and are not in either of these groupings.

ARGUMENTS

Claims 13-16 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Brine (U.S. Patent No. 5,075,115). Specifically, the Examiner contends that Brine teaches polymers of lactic acid with a molecular weight of 2500-4500, specifies terpolymers with other hydroxycarboxylic acids such as glycolic acid, ϵ -caprolactone, and valerolactone (column 3, lines 28-32), and discloses glass transition temperatures of 26°C to -65°C (column 3, lines 52-53).

A terpolymer is a polymer made from three different monomers. Brine does not teach or describe terpolymers at all. Furthermore, Brine does not teach the specific terpolymers of monomer units derived from lactic acid, glycolic acid, and caprolactone or valerolactone, as required by claims 13-16. Therefore, applicants respectfully submit that the rejection based on Brine is improper.

Anticipation exists only if all the elements of the claimed invention are present in a product or process disclosed, expressly or inherently, in a single prior art reference.

Hazeltine Corp. v. RCA Corp., 468 U.S. 1228 (1984). The Examiner contends that Brine teaches terpolymers of lactic acid with other hydroxycarboxylic acids. As discussed above, Brine makes no mention whatsoever of terpolymers. Rather, Brine teaches poly(lactic acid) and poly(lactic acid) mixed with copolymers or homopolymers of other acids. The specification at col. 3, lines 28-32, as cited by the examiner, refers to a process for

polymerizing lactic acid to poly(lactic acid) and states that “the present invention is intended to include the product made by the process as well as copolymers and mixtures of polymers of glycolic acid, valerohydroxycarboxylic lactone, ϵ - caprolactone, ϵ - decalactone, hydroxybutyric acid, β - hydroxyvaleric acid and dioxanone” Brine’s Examples 1 and 2 teach a blend of a poly(DL-lactic acid) polymer and a polycaprolactone polymer, and Table 1, entitled “Polymer Overview,” teaches only poly(L-lactic acid), poly(DL-lactic acid), and polycaprolactone polymers.

Applicants acknowledge that there is some teaching in Brine of copolymers, but the copolymers taught by Brine are copolymers of lactic acid “with glycolic acid, valerolactone, decalactone, or the like . . . such as racemic lactic acid with glycolic acid, or 1(+)-lactic acid with valerolactone.” (Column 4, lines 60-64, emphasis added.) Thus, the only copolymers taught by Brine are copolymers that use two different monomers, and these are not terpolymers. There simply is no teaching or suggestion in Brine to use three different monomers, let alone the particular terpolymers of poly(lactide/glycolide/caprolactone) or poly(lactide/glycolide/valerolactone). A required element of the invention of claims 13-16 is a lactide-containing terpolymer consisting of monomer units selected from the group consisting of lactic acid, glycolic acid, and caprolactone or valerolactone. Respectfully, Brine cannot be said to anticipate claims 13-16.

Furthermore, claims 13-16 specify that the claimed terpolymers exhibit an “adhesive strength of about 600 to about 150,000 Pa” such that they can be used as pressure sensitive adhesives for tissue repair. Brine discloses the use of poly(lactic acid) in dosage forms for the controlled release of pharmaceutically active compounds. Brine is silent on the characteristics of the disclosed poly(lactic acid) compositions. Applicants’ claimed polymers are sticky and sticky polymers would complicate (gum up the machine) the tableting of, for example, tableting compositions used to prepare tableted controlled release dosage forms. Further, the polymer compositions taught by Brine (to be used as taught by Brine) necessarily have properties different than the polymers of the present invention. A person skilled in the art simply would not take Brine’s teaching of copolymers for controlled release dosage forms

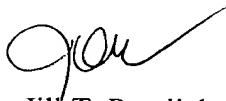
and arrive at the specific terpolymers of claims 13-16. Therefore, Brine cannot reasonably be said to anticipate claims 13-16.

In sum, Brine (U.S. Patent No. 5,075,115) does not describe lactide-containing terpolymers of monomer units derived from lactic acid, glycolic acid, and caprolactone or valerolactone, nor does the reference describe or suggest such polymers capable of ~~functioning as pressure sensitive adhesives for tissue repair.~~ Brine, therefore, cannot reasonably be said to anticipate claims 13-16. Reconsideration of the rejection of claims 13-16 under 35 U.S.C. § 102(b) leading to reversal of the Examiner's rejection and passage of the application to issuance is respectfully requested.

Claim 13-18 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite. In particular, the Examiner contends that the term "derived" is vague and that it is unclear as to whether derivatives of the recited hydroxy carboxylic acids are intended.

Applicants have previously stated that monomer derivatives of the recited hydroxy carboxylic acids are not intended by this claim language. The language "derived from" was used to impart precision to the claim language. Once the monomer units of lactic acid, glycolic acid, and either caprolactone or valerolactone are polymerized, they are no longer monomer units of these hydroxy carboxylic acids. Rather, once polymerized, the units are derived from monomer units of lactic acid, glycolic acid, and either caprolactone or valerolactone. Applicants believe that the examiner's suggested language is inaccurate, as the polymer is not "comprised of" monomer units of lactic acid, glycolic acid, and either caprolactone or valerolactone. Reconsideration of the rejection leading to reversal of the Examiner's rejection and passage of the application to issuance is respectfully requested.

Respectfully submitted,



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Appendix
Claims 1-12 stand allowed
Claims 13-18 stand finally rejected and are appealed

1. A pressure sensitive adhesive for tissue repair comprising a thermoplastic lactide-containing terpolymer consisting of monomer units derived from lactic acid, glycolic acid, and either caprolactone or valerolactone, said terpolymer having an average molecular weight of 1,000 to 3,000, exhibiting an adhesive strength of about 600 to about 150,000 Pa, and having a water solubility of 0.01 to about 500 mg/ml at about 25°C.
2. The pressure sensitive adhesive of claim 1 wherein terpolymer is poly(lactide/glycolide/caprolactone).
3. The pressure sensitive adhesive of claim 1 wherein the terpolymer is poly(lactide/glycolide/valerolactone).
4. The pressure sensitive adhesive of claim 3 wherein the terpolymer comprises about 35-45% lactide, about 35-45% glycolide, and about 10 to about 30% valerolactone.
5. The pressure sensitive adhesive of claim 1 wherein the terpolymer has a glass transition temperature of less than 0°C.
6. The pressure sensitive adhesive of claim 1 further comprising a filler.
7. The pressure sensitive adhesive of claim 6 wherein the filler is selected from the group consisting of bone chips, tricalcium phosphate, hydroxylapatite, small intestine submucosa, bioglass granules, synthetic polymers, calcium carbonate, calcium sulfate and collagen.
8. The pressure sensitive adhesive of claim 1 further comprising a bioactive agent.
9. The pressure sensitive adhesive of claim 8 wherein the bioactive agent is a growth factor.

10. The pressure sensitive adhesive of claim 9 wherein the growth factor is selected from the group consisting of a fibroblast growth factor, a transforming growth factor, a bone morphogenetic protein, an epidermal growth factor, a platelet-derived growth factor, and an insulin-like growth factor.

11. A pressure sensitive adhesive for tissue repair comprising a thermoplastic lactide-containing terpolymer consisting of monomer units derived from lactic acid, glycolic acid, and either caprolactone or valerolactone, said terpolymer having an average molecular weight of 1,000 to 2,500, exhibiting an adhesive strength of about 600 to about 150,000 Pa and having a water solubility of 0.01 to about 500 mg/ml at about 25°C.

12. A pressure sensitive adhesive for tissue repair comprising a thermoplastic lactide-containing terpolymer consisting of monomer units derived from lactic acid, glycolic acid, and either caprolactone or valerolactone, said terpolymer being a moldable putty, having an average molecular weight of 1,000 to 3,000, exhibiting an adhesive strength of about 600 to about 150,000 Pa and having a water solubility of 0.01 to about 500 mg/ml at about 25°C.

13. A pressure sensitive adhesive for tissue repair comprising a thermoplastic lactide-containing terpolymer of monomer units derived from lactic acid, glycolic acid, and either caprolactone or valerolactone, said terpolymer having an average molecular weight of 1,000 to 3,000, exhibiting an adhesive strength of about 600 to about 150,000 Pa, having a water solubility of 0.01 to about 500 mg/ml at about 25°C, and having a glass transition temperature of less than 0°C.

14. A pressure sensitive adhesive for tissue repair comprising a thermoplastic lactide-containing terpolymer of monomer units derived from lactic acid, glycolic acid, and either caprolactone or valerolactone, said terpolymer having an average molecular weight of 1,000 to 3,000, exhibiting an adhesive strength of about 600 to

about 150,000 Pa, and having a water solubility of 0.01 to about 500 mg/ml at about 25°C;
and

a filler.

15. The pressure sensitive adhesive of claim 14 wherein the filler is selected from the group consisting of bone chips, tricalcium phosphate, hydroxylapatite, small intestine submucosa, bioglass granules, synthetic polymers, calcium carbonate, calcium sulfate and collagen.

16. A pressure sensitive adhesive for tissue repair comprising
a thermoplastic lactide-containing terpolymer of monomer units derived from lactic acid, glycolic acid, and either caprolactone or valerolactone, said terpolymer having an average molecular weight of 1,000 to 3,000, exhibiting an adhesive strength of about 600 to about 150,000 Pa, having a water solubility of 0.01 to about 500 mg/ml at about 25°C; and
a bioactive agent.

17. The pressure sensitive adhesive of claim 16 wherein the bioactive agent is a growth factor.

18. The pressure sensitive adhesive of claim 17 wherein the growth factor is selected from the group consisting of a fibroblast growth factor, a transforming growth factor, a bone morphogenetic protein, an epidermal growth factor, a platelet-derived growth factor, and an insulin-like growth factor.